

PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing: 18 September 1997 (18.09.97)	
International application No. PCT/AU97/00161	Applicant's or agent's file reference PN8703/EJH/AF
International filing date: 14 March 1997 (14.03.97)	Priority date: 14 March 1996 (14.03.96)
Applicant: COWDEN, William, Butler et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International preliminary Examining Authority on:
30 July 1997 (30.07.97)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer: J. Zahra
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 21 NOV 1997

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PN8703/EJH/AF	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU 97/00161	International filing date 14 March 1997	Priority Date 14 March 1996
International Patent Classification (IPC) or national classification and IPC Int. Cl.⁶ A61K 39/118, 39/02		
Applicant (1) THE AUSTRALIAN NATIONAL UNIVERSITY (2) COWDEN, William Butler et al.		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 5 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 30 July 1997	Date of completion of the report 7 November 1997
Name and mailing address of the IPEA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer R.L. POOLEY Telephone No. (02) 6283 2242

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☒ the international application as originally filed.

☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , filed with the letter of ,
 pages , filed with the letter of .

☐ the claims, Nos. , as originally filed,
 Nos. , as amended under Article 19,
 Nos. , filed with the demand,
 Nos. , filed with the letter of ,
 Nos. , filed with the letter of .

☐ the drawings, sheets/fig , as originally filed,
 sheets/fig , filed with the demand,
 sheets/fig , filed with the letter of ,
 sheets/fig , filed with the letter of .

2. The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

Please note that Claims 1 to 14 are subject matter of rule 67.1 (i.e., methods of treatment of humans) and as such do not require an international preliminary examination. However, because the subject matter does not contravene Australian Patent Law these claims have been considered in the examination.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 9-14	YES
	Claims 1-8, 15-28	NO
Inventive step (IS)	Claims 9-14	YES
	Claims 1-8, 15-28	NO
Industrial applicability (IA)	Claims 1-28	YES
	Claims	NO

2. Citations and explanations

The following documents, cited in the ISR, remain relevant:

- D1 Acta Virilogica (English Edition), Volume 38, No. 6 (1994), pages 327-332, Y X Zhang et al.,
- D2 Acta Virilogica (English Edition), Volume 38, No. 6 (1995), pages 339-344, E Gajdosova et al.,
- D3 Clinical and Experimental Immunology, Volume 94, No. 3 (December 1993) pages 507-515, A A Izzo et al.,
- D4 The Medical Journal of Australia, Volume 160, No. 11 (6 June 1994), pages 704-708, J R Ackland et al.,
- D5 Revue d'élevage et de médecine vétérinaire des pays tropicaux, Volume 46, Nos (1-2), (1996) pages 87-94, J C Williams et al.,
- D6 Mims' Annual (1993), page 10-553
- D7 Derwent Abstract Accession No. 95-244760/32, RU 2026342 C
- D8 Derwent Abstract Accession No. 93-098731/12, SU 1724683 A
- D9 Respiration, Volume 62, No. 2 (1995) pages 114-116, K Kayser et al.,

NOVELTY (N): Claims 1-8, 15-28

The cited documents D1, D2, D3, D4, D5, D6, D7 and D8 all disclose compositions comprising Coxiella and/or antigenic components thereof, including Q fever antigen, as well as their pharmaceutical application. These compositions would be capable of use in the prevention, inhibition or delayed onset of autoimmune disease. Consequently Claims 15-28 lack novelty in light of these citations.

Note that Claim 15 has been construed to only require the composition to be capable of the specified use, and not restricted to that use. Claim 22 has been construed to only limit the use of the Coxiella to the manufacture of the medicament, with that medicament being capable of the specified use.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : Box V

Furthermore, there is no distinction between the locus of treatment of claim 1, and that of the citations. The mammal of Claim 1 is not restricted to a mammal in need of prevention/treatment of an autoimmune disease, and hence could include the same mammals to which the vaccines of the prior art are administered. Consequently Claims 1-8 lack novelty in light of these documents.

INVENTIVE STEP (IS): Claims 1-8, 15-28

Claims 15-28: as above.

Claims 1-8: as above.

In addition, documents D1-D8 and D9 when combined, as would be obvious to a skilled person, disclose all the features of Claims 1-8. Document D9 of Kayser describes a case of a patient having chronic Q fever, and states that such a manifestation of Q fever may induce changes in the immune system comparable to autoimmune reactive diseases. Coxiella and its antigenic components are disclosed in documents D1-D8 as vaccines for preventing Q fever. The suggestion in Document D9 of the close relationship between Q fever and various autoimmune diseases would lead a skilled person to try similar treatments for the prevention of these conditions. Thus a skilled person would at least be led to try the known Q fever vaccines of documents D1-D8 in the prevention or inhibition of autoimmune disease, and claims 1-8 consequently lack inventive step from the combined disclosures of these documents.

None of the above documents suggest the use of Coxiella for prolonging survival of transplanted islet tissue. Claim 9 restricts the locus of the treatment to a mammal in which the tissue has been transplanted and is consequently distinguished from the prior art disclosures.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- (a) Claims 1, 9, 15 and 22 are unclear because the ambit of the analogous or homologous components is indefinite. The description at page 7 lines 19-20 indicates that these components include those which are functionally the same as Coxiella and its antigens. However the extent to which these components may be structurally different from Coxiella and its antigens has not been defined, and it would require an undue burden of experimentation for a skilled person to determine the range of antigens which could be included within the ambit of these terms.
- (b) Claims 22-28 are unclear because it is unclear whether:
 - (i) they are directed only to the manufacture of a medicament or
 - (ii) whether they are directed both to the manufacture of a medicament and its use in the treatment of an autoimmune disease in a mammal.

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00161

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl⁶: A61K 39/118, 39/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC : A61K 39/118, 39/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DERWENT : COXIELLA
CA & MEDLINE : COXIELLA and (autoimmun: or diabet: or iddm or islet: or pernicious () anaemia or ulcerative () colitis or lupus or Biliary () cirrhosis or multiple () sclerosis)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	Acta Virilogica (English Edition), Volume 38, No. 6, (1994), Prague, Czech Republic, Y.X Zhang et al, "Protective Immunity Induced by 67K Outer Membrane Protein of Phase 1 Coxiella Burnetii in Mice and Guinea Pigs", pages 327-332.	15-28 1-9
X Y	Acta Virilogica (English Edition), Volume 38, No. 6, (1995), Prague, Czech Republic, E. Gajdosova et al, "Immunogenicity of Coxiella Burnetii whole cells and their outer membrane components", pages 339-344.	15-28 1-8

☒ Further documents are listed in the continuation of Box C

☐ See patent family annex

* Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
16 June 1997

Date of mailing of the international search report

23.06.1997

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 97/00161

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	Clinical and Experimental Immunology, Volume 94, No. 3, (Dec. 1993), United Kingdom. A.A. Izzo et al, "Variation in interferon-gamma responses to Coxiella Burnetii antigens with lymphocytes from vaccinated or naturally infected subjects", pages 507-515.	15-28 1-8
X Y	The Medical Journal of Australia, Volume 160, No. 11, (6 June 1994), Australia, J.R. Ackland et al. "Vaccine prophylaxis of Q Fever : A follow-up Study of the efficacy of Q-Vax (CSL) 1985-1990", pages 704-708.	15-28 1-8
X Y	Revue d'elevage et de medecine veterinaire des pays tropicaux, Volume 46, Nos (1-2), (1993), Paris, France, J.C. Williams et al, "Immunisation of dogs with Q fever vaccines : comparison of phase 1, 11 and phase 1 CMR Coxiella Burnetii vaccines", pages 87-94.	15-28 1-8
X Y	Mims Annual, published 1993 by Mims Australia, Sydney, Australia, page 10-553.	15-28 1-8
X Y	Derwent Abstract Accession No. 95-244760/32, Class D16, RU, 2026342, C1, (Leningrad Epidermiology Microbial Research Institute) 10 January 1995	15-28 1-8
X Y	Derwent Abstract Accession No. 93-098731/12, Class B04, D16, SU, 1724683, A (Leningrad Epidemiology Microbial Research Institute) 7 April 1992	15-28 1-8
Y	Respiration, Volume 62, No. 2, (1995), Basel, Switzerland, K. Kayser et al. "Necrotizing Bronchitis, Angiitis and Anyloidosis Associated with Chronic Q Fever". pages 114-116. See especially the abstract, last sentence.	1-8
A	AU, 59600/96, A (Nextar Pharmaceuticals Inc.) 19 December 1996 (& WO, 96/40235, A).	